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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/565,673	08/10/90	VAN DER LAAN	J 34363/GBRO-0

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EXAMINER	
HENDRICKS, K	
ART UNIT	PAPER NUMBER
1814	44

DATE MAILED: 04/01/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12-26-96

☒ This action is FINAL.

Note ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 months month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 4-7, 9-10, 12-14, 19, 23-25, 29-35 & 38-40 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 4-7, 9-10, 12-14, 19, 23-25, 29-35 & 38-40 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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Part III DETAILED ACTION

Claim Rejections - 35 USC § 112

112 1st Paragraph

5 The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention,
and of the manner and process of making and using it, in such full,
clear, concise, and exact terms as to enable any person skilled in the
art to which it pertains, or with which it is most nearly connected, to
10 make and use the same and shall set forth the best mode contemplated by
the inventor of carrying out his invention.

15 Claims 4-7, 9-10,12-14, 19, 23-25,29, 30-35 and new 38-40 are rejected
under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for
claims limited to methods of producing an alkalophilic asporogenic *Bacillus*
15 *novo* species PB92 of minimal natural extracellular protease level, transformed
with a *Bacillus* PB92 alkaline protease which has been mutated as described in
the specification. See M.P.E.P. §§ 706.03(n) and 706.03(z).

20 Contrary to applicants' arguments of 12-26-96, the assertion at pages 8-10
that the rejection is merely a matter of breadth is incorrect. The Examiner
and Patent Office does not possess the facilities to test and screen other
Bacillus strains and high alkaline protease genes for their obtainability,
production and use within the claimed system. The Examiner has repeatedly,
however, set forth a reasonable rejection, based upon the facts, and taking
into account the factors necessary to determine enablement. A number of
25 factors must be considered in assessing the enablement of an invention,
including the following: the breadth of the claims, the amount of
experimentation necessary, the guidance provided in the specification, working
examples provided, predictability, and the state of the art. See *In re Wands*,
858 F.2d 731, 8 USPQ2nd 1400 (Fed. Circ. 1988).

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The breadth of the claims encompass the use of any high alkaline protease gene from any *Bacillus* strain. Applicants then must be asserting that given their invention, one skilled in the art could isolate, produce and utilize any high alkaline protease gene from any *Bacillus* strain. Applicants must be asserting that they teach one skilled in the art how to perform such tasks. Applicants must be asserting that this would not require any undue experimentation, that it would not involve any inventive application, and that in fact, it would be relatively routine to do so. Applicants, however, have demonstrated one single high alkaline protease gene. It is unclear, then, how one skilled in the art is to utilize this information, in order to extrapolate these limited teachings to screen, locate, isolate, produce and utilize any other such gene. The teachings simply do not exist within the specification. While the state of the art regarding cloning of genes was relatively skilled, the predictability would be low, while the amount of experimentation would be extremely high to one skilled in the art, given the limited or lack of guidance toward other genes. The same standards apply to the mutations encompassed by the proteases within the invention of claims 19,24-25 and 38-40, as again, the specification is not properly enabled for the phrase "mutated high alkaline protease". The predictability of the results of such random and non-specific mutations is extremely low, as well as the experimentation level for such random mutations is very high.

Further, the same principles apply to other alkalophilic strains of *Bacillus*. In order to produce the instant invention, one skilled in the art would not only have to have knowledge of the high alkaline protease gene (sequence, clone, etc.) necessary to mutate and insert into the alkalophilic *Bacillus* host, as described above, but one would also have to possess the same knowledge regarding the wild-type gene of said alkalophilic *Bacillus* host, in order to delete said gene to produce "a non-reverting alkalophilic *Bacillus*

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strain host which produces no detectable wild-type extracellular high alkaline protease endogenous" to said strain. In other words, one skilled in the art would have to master all facets necessary for two different genes high alkaline protease genes, not just one, as encompassed by the claims. Applicants have demonstrated one single high alkaline protease gene. Thus, not only is applicants' claimed invention non-enabling for merely any *Bacillus* high alkaline protease gene, but also any alkalophilic *Bacillus* host other than the demonstrated PB92, because the experimentation left to one skilled in the art as described in the preceding paragraph would actually be doubled.

Thus, this is not simply a matter of "generically claimed proteins [or genes] and generically claimed bacteria", as stated at pages 9-10, citing *In re Vaeck*. Initially, it can be appreciated that the disclosure of Vaeck is different from applicants disclosure, and the enablement provided therein would be expected to differ significantly, based upon the field of art and the disclosure presented. Nor is this simply a matter of a mere production of analogs of a given chemical structure, wherein one skilled in the art is provided a great amount of detail of the other compounds encompassed. In the instant case, one skilled in the art is provided with absolutely no detail or guidance toward any other compound, i.e. high alkaline protease gene. Also unlike Vaeck, the boundaries of the possible number of high alkaline protease genes has not been set forth by applicants; therefore a great deal of unpredictability and experimentation exists.

Finally, at page 9, applicants state that "the Examiner has not provided a single example of an alkalophilic *Bacillus* or a mutated high alkaline protease which would not function in any of the claimed inventions". Initially, however, this is not the standard, as non-operative embodiments may be included in the claims, and the Examiner has not attempted to hold

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5 applicants to such criterion. Secondly, the Examiner is not required to demonstrate the existence of other strains or genes which would be encompassed by the claims. In fact, this would be contrary to the Examiner's position: that the knowledge and obtainability of any other such gene or strains with
10 their respective genes, is not common, is not known in the art, and not within the level of skill in the art given applicants' disclosure. Apart from the single example of *Bacillus* PB92, it does not appear that applicants have "provided a single example [or evidence or guidance] of an alkalophilic *Bacillus* or a mutated high alkaline protease which" would "function in any of the claimed inventions".

The rejection remains for the reasons of record.

15 Again and importantly, there is no teaching or reasonable expectation provided that one skilled in the art would be able to utilize the teachings provided for any other systems/genes, or even that there is a problem with any other source such that the instant invention would be applicable. Absent this knowledge, one skilled in the art is left with an undue amount of
20 experimentation, due to the breadth of the claims, in order to attempt to determine what other Bacilli or proteases would be useful in the instant invention, and then further attempt to find the gene and apply the principles taught herein. The specification has not provided pertinent information regarding any other "high alkaline protease" gene, nor any appropriate Bacillus strain that would satisfy the requirements of the invention. This fact is
25 important, as the claims are not commensurate in scope with the specification and its enablement. This information is essential to the function of the claimed invention, and the essential material may not be improperly incorporated into the specification, and does not find support within the teachings of the specification. Thus, one skilled in the art would in no way
30 be enabled to practice the claimed invention with any such gene or strain other than the enabled Bacillus PB92.

35 Applicants have attempted to add support to the argument by incorporating the statement at page 12 of the specification regarding B. lentus. The Examiner does not see how this statement within the specification provides one skilled in the art with enablement to make and/or use the invention with such

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5 a strain. This passage does not appear to connect and directly dictate the use of this strain in the instant method, nor does it provide a reasonable expectation of success, predictability or guidance to use this strain. Even if this were true, the amount of experimentation for one skilled in the art to test this strain, given the parameters discussed in the paragraph above, would be undue, and would not provide enablement for the breadth of the instant claims.

10 Again, the specification is not properly enabled for claims to any "derivative thereof" of a Bacillus novo species PB92. Applicants state that passages on page 12 of the specification refer to known "derivatives", and that this would be enabling for the instant invention. The phrase "derivatives thereof", however, encompasses predetermined and random mutants of the strain, and progeny of the strain that may or may not contain the gene for the "mutant
15 high alkaline protease" and/or a revertant strain with the indigenous gene. The specification does not properly teach nor describe to one skilled in the art these "derivatives", what specifically they entail, nor how to obtain and/or use such. Mere reference to other teachings, when this is a matter of essential material, without an instant and specific teaching as to how these
20 would be applicable, is not sufficient. Thus, this results in undue experimentation for one skilled in the art to attempt to produce such without proper guidance from the specification. As of the amendment of 12-26-96, applicants have stated that because claim 30 recites the various characteristics of PB92 as the host strain, that any derivative must have these
25 characteristics. This is not deemed persuasive, because it is potentially incorrect. If applicants wish to add the phrase "which retains all of the identifying characteristics of the parent strain", or some similar recitation enabled by the specification, then this would serve to overcome the rejection at hand. However, applicants' conclusion that it would necessarily retain
30 these characteristics has no basis; a derivative may differ significantly, and

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thus may not retain all of the parents' characteristics. NOTE that this issue also exists in claim 13.

5 **112 2nd Paragraph**

Claim 38 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10 Claim 38 is indefinite for the recitation of the phrase "In detergent composition". It is suggested that this be amended to recite "A detergent composition".

15 ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

20 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by
30 the same person or subject to an obligation of assignment to the same person.

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Claims 19,24-25 and new 38-40 are rejected under 35 U.S.C. § 103 as being unpatentable over Fahnestock et al. and Estell et al., in view of TeNijenhuis and Suggs et al. The references and rejection are herein incorporated as cited in a previous Office Action.

5 Applicants' arguments filed 12-26-96 have been fully considered but they are not persuasive. Applicants have stated that there is no motivation to combine the references, and no expectation of success.

10 The claims are directed to: detergent compositions, methods of making and methods of using, all employing one single compound --- "a mutant from of high alkaline protease". The claims are not directed to methods of producing such a protease. The claims are not directed to methods of producing a *Bacillus* strain containing the protease. They are directed to that stated above, only. If the generically-mutated alkaline protease was found elsewhere in the prior art, regardless of method (applicants' or otherwise), and motivation to combine
15 such with a detergent composition and methods existed, then the instant claims would be unpatentable. Applicants' method of producing the protease (claim 23, etc.), as previously stated, appears to have no bearing upon the patentability of the protease itself, i.e. the protease may already be known, while applicants may still have novel and unobvious claims to methods of producing
20 such. This is the case.

25 Since the mutations are random and non-specific, again, TeNijenhuis describes the natural protease, and various naturally-occurring mutations would have been expected to occur. Also see *Ex parte Anderson*, 30 USPQ2d, (BPAI, 1994)1866. Estell et al. describe the use of mutated alkaline proteases within detergent compositions, as well as methods of making and using such. TeNijenhuis teach the use of the *Bacillus* PB92 protease within cleaning compositions and methods. This was well known in the art to do at the time the invention was made. Thus, a teaching of the protease of the instant

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compositions was known, and a teaching of using mutated alkaline proteases within laundry detergents was known. The combination of the two would have been obvious to one of ordinary skill in the art, and the expectation of successfully producing the instantly claimed invention would have been high. The limitation of "no detectable wild-type high alkaline protease" within the composition of the protease (new claims 38-40) does not appear to impart a patentable distinction to the claims, as the reference of TenNijenhuis teaches recovery of the enzyme, and further purification of such would have been an obvious step, as this was important and common in the art at the time the invention was made.

Again, applicants have received patents (5,336,611 and 5,324,653) directed to specific novel and unobvious mutations of the protease, genes, etc. The instant proteases are not directed nor limited to such mutations.

Conclusion

Claims 4-7, 9-15, 23 and 26-34 are free of the prior art. Applicants' arguments have been deemed persuasive.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

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NO CLAIM IS ALLOWED.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703)308-2959.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose phone number is (703)308-0196.


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kdh
March 31, 1997


KEITH D. HENDRICKS
PRIMARY EXAMINER
GROUP 1800